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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,381	04/17/2001	Mikiko Suga	206018US0	5139

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ALEXANDRIA, VA 22314

EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/835,381

Applicant(s)

SUGA ET AL.

Examiner

Christian L Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,6,7,9,10,12,13,15,16 and 18-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.

- 6) ☒ Claim(s) 2,3,6,7,9,10,12,13,15,16 and 18-23 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1652

DETAILED ACTION

1. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-23 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-23 are rejected under 35 USC 101 because the claimed invention is directed to non-statutory subject matter.

Applicants' position is that amending the claims to recited "isolated" renders the invention as statutory subject matter. However, the claims as written, do not sufficiently distinguish over bacterial cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed bacteria and the naturally occurring bacteria - the claimed bacteria read on naturally occurring bacteria having a disrupted and inactivated *argR* gene. The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "transformed" or "recombinant". See MPEP 2105.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1652

The claims are directed to any coryneform bacteria having any *argR* gene obtained from PCR with primers of SEQ ID NO: 15 and SEQ ID NO: 16. However, the specification discloses only a single representative species encompassed by these claims: a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17. There is no written description for the all the PCR products obtainable from PCR using primers of SEQ ID NO: 15 and SEQ ID NO: 16 which are expected to be vary greatly in structure and nucleotide sequence since not specific PCR conditions have been recited.

Given the lack of written description PCR products obtainable from PCR using primers of SEQ ID NO: 15 and SEQ ID NO: 16, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

6. Claims 2, 3, 6, 7, 9, 10, 12, 13, 15, 16, and 18-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any coryneform bacterium having any *argR* of any nucleotide sequence obtained from PCR using primers of SEQ ID NO: 15 and SEQ ID NO: 16. The specification provides guidance and examples in making a *Brevibacterium lactofermentum* strain containing a disruption of the *argR* gene, wherein said *argR* gene consists of the nucleotide sequence of SEQ ID NO: 17 and said strain is identified as strain AJ13029deltaR.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the specific coryneform bacterium having any disrupted *argR* gene that has a nucleotide sequence derived from PCR products using primers of SEQ ID NO: 15 and SEQ ID NO: 16 which are expected to be vary greatly in structure and nucleotide sequence since not specific PCR conditions have been recited is lacking. Thus, searching for such coryneform bacterium is well outside the realm of

Art Unit: 1652

routine experimentation and predictability in the art of success is extremely low.

The amount of experimentation to make the claimed bacterium is enormous entails isolating chromosomal DNA from any species of coryneform bacteria out of a vast number of species, performing PCR using primers of SEQ ID NO: 15 and SEQ ID NO: 16 under any given PCR conditions and determining whether the PCR product encodes the claimed disrupted argR gene product. Since routine experimentation in the art does not include the enormous amount of experimentation stated above where the expectation of obtaining the desired species of coryneform bacteria is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as the specific nucleotide sequence of the PCR product which encodes the disrupted argR gene product. Without such a guidance, the experimentation left to those skilled in the art is undue.

Conclusion

7. No claim is allowed.


8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

09835381.400


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